

**GRANT PROPOSAL: DEFINING LOW BACK PAIN RECURRENCE TO EVALUATE
SECONDARY PREVENTION OF OCCUPATIONAL LOW BACK PAIN**

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Abstract

The public health significance of low back pain results from the economic and social burdens it places on industrialized societies. The primary objective of this paper is to create a definition of low back pain recurrence based on present scientific literature. No unified definition has been offered in current research and a universally accepted definition will help advance the study and treatment of low back pain recurrence. The need for a unified definition comes from the fact it is not easy to compare the various studies of recurrent low back pain. This limitation affects the treatment patients are given and the outcomes they experience.

Building on our primary objective of creating a unified definition of low back pain we will then take the definition and use it to evaluate available databases (UPMC Health Plan and Workers' Compensation) for low back pain recurrence. The definition and the available data will be used to evaluate the costs, both direct (medical and workers' compensation) and indirect (related to lost work time, etc, associated with low back pain). This will be useful in comparing the medical and personnel costs aspects of patients with recurrent low back pain to those without recurrent low back pain. By performing this analysis we will be able to estimate the costs savings of effective treatment for low back pain recurrence.

Using the definition of low back pain recurrence developed and the data and clinical resources available we will develop an intervention to reduce recurrence rates of work related low back pain. Specific treatment groups will be identified and compared in a prospective analysis to the usual care low back pain patients receive. The results of this aspect of the study will be used to decide if the proposed treatment was able to reduce medical and other costs as predicted when compared to any increased costs specific treatments may entail.

Finally, the rationale for a new universally accepted definition of recurrent low back pain will be given. I will then give a brief outline of a step-wise process to be used by future researchers in addressing recurrent low back pain.

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PREFACE

I would like to acknowledge the guidance, help, and support for this project given to me by Dr. Anthony Delitto. Through his expertise and time I was able to create this thesis which we hope will be invaluable in helping to further the study and treatment of patients with recurrent low back pain. As you will see it can be a very complicated and controversial area of study with many proposed definitions and resolutions, none of which at this point have reached the level of universal acceptance which this area of study so drastically needs.

At this time I feel it is necessary to describe the background that went in to this project and the final stage in which we now see it. This research initially started and is ultimately intended to be used in the writing of a grant proposal to define and study recurrent low back pain. The necessity of submitting it in an electronic format for the University Of Pittsburgh Graduate School Of Public Health is what leads it to the present incarnation you see before you. I feel this is an acceptable transition from a grant proposal format to a thesis format which will make it easier to read and understand for all involved. The process as we have envisioned it will be a multistep research process which will take several years to complete.

Finally, acknowledgement and appreciation must be given to my wife, Mary Beth, for putting up with my time spent on this project. More importantly I must thank her for the time she had to spend listening to me grumble about the slow progress I felt I was making. Also, to Dr. Joseph Schwerha, my program director and mentor I would like to thank you for the constant

support you have given me through the past two years and for keeping me on track. Dr. Thomas Songer has contributed to this work with his advice and comments. He was able to help me on short notice and for that alone he deserves much thanks and appreciation.

1.0 SPECIFIC AIMS

1.1 PRIMARY OBJECTIVES

This grant proposal is envisioned as a three step process. The primary objective of this paper is to create a definition of work related low back pain recurrence based on the present scientific literature. No unified definition has been offered so far in current research and a universally accepted and applicable definition will help advance the study and treatment of low back pain recurrence. The need for a unified definition comes from the fact that it is not easy to compare the various studies of recurrent low back pain. This limitation can affect the treatment patients are given and ultimately the outcomes they experience.

1.2 SECONDARY OBJECTIVES

Building on our primary objective of creating a unified definition of low back pain we will then be able to take the definition and use it to evaluate available databases (UPMC Health Plan and Workers' Compensation) for low back pain recurrence. The definition we establish and the available data will be used to evaluate the costs, both direct (medical and workers' compensation) and indirect (related to lost work time, etc, associated with low back pain). This

will be useful in comparing the medical and personnel costs aspects of patients with recurrent low back pain to those without recurrent low back pain. By performing this analysis we will be able to estimate the costs savings (direct and indirect) of effective treatment for low back pain recurrence.

Finally, using the definition of low back pain recurrence developed and the data and clinical resources available we will develop an intervention to specifically reduce recurrence rates of work related low back pain. Specific treatment groups will be identified and compared in a prospective analysis to the usual care low back pain patients receive. The results of this aspect of the study will then be used to decide if the proposed treatment was able to reduce medical and other costs as predicted when compared to any increased costs specific treatments may entail.

2.0 BACKGROUND AND SIGNIFICANCE

Low back pain is a term used by researchers, clinicians, and the general public on a daily basis. The problem is that what low back pain means to one group is different from what it means to the others. As this paper will help to explain it often means different things to people within each of those groups. This can lead to misunderstandings and confusion. One confusing aspect is that researchers and clinicians talk about low back pain recurrence in addition to episodes of low back pain. Again there is often no clearly accepted definition between and within the groups as to what constitutes a low back pain recurrence. This creates a problem for health care professionals and others when trying to evaluate research on the best course of treatment for patient outcomes and costs savings for low back pain.

When the term low back pain is used it generally means an episode of pain in the lower back which is often related to a specific precipitating event. The term low back pain recurrence often means another episode of pain in the lower back which is related to the original episode of pain and occurs after that episode has resolved. These are general definitions only and can not easily be applied to research when evaluating for treatment efficacy and cost savings.

2.1 GENERAL ANATOMY AND THE PATHOPHYSIOLOGY OF LOW BACK PAIN

The lower back is composed of a variety of structures. These include the bony structures which are typically the five lumbar vertebrae, the sacrum and coccyx. There are also the intervertebral discs and ligamentous structures of the spine as well as the paraspinous muscles, nerves, and blood vessels.

The lumbar vertebrae articulate with each other at anterior and posterior intervertebral joints. They are stabilized by ligaments anteriorly and posteriorly(Moore, 1992). A single vertebra consists of many distinct parts. Anteriorly is the vertebral body which then progresses to the pedicles and the lamina which form a canal called the vertebral foramen. The spinal cord and its surrounding structures are found within the vertebral foramen or spinal canal. Laterally the vertebrae have transverse processes and posteriorly there is a spinous process. These structures serve as attachment points for the various ligaments and muscles of the back. Two vertebrae in articulation have vertebral notches, which are indentations of the pedicles, which form the intervertebral foramen(Moore, 1992). The intervertebral foramina are where the nerve roots exit the spinal column. The sacrum is formed from the fusion of 5 sacral vertebrae and the coccyx is a vestigial remnant of bone.

The following figures show a typical vertebra. Figure 1 is from the superior view and Figure 2 is from a lateral view.

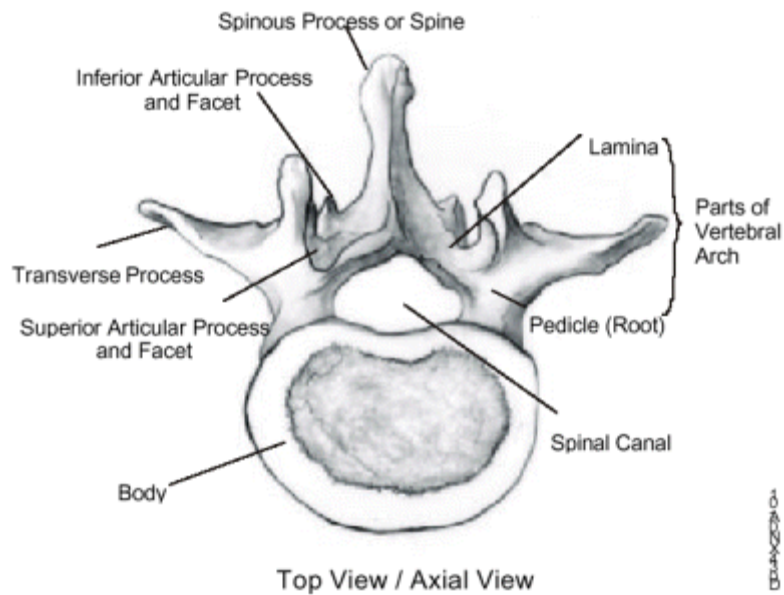


Figure 1. Superior view of a vertebra

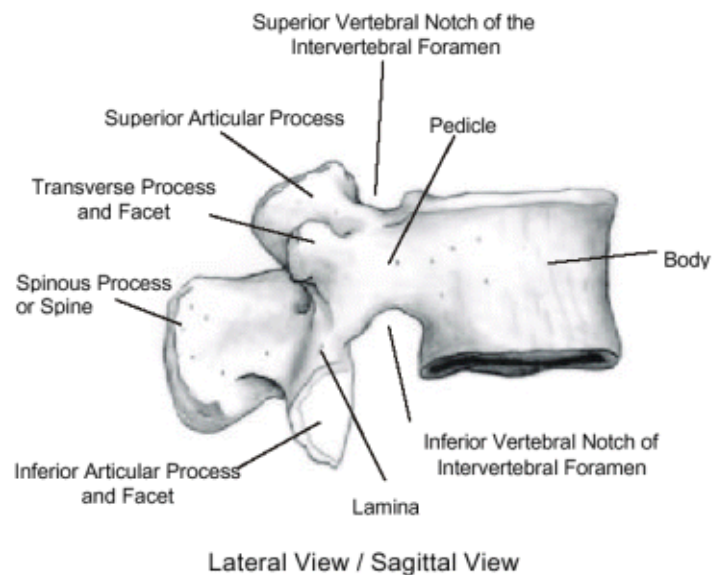


Figure 2. Lateral view of a vertebra

Figure 3 is an oblique view of several vertebrae as they would appear anatomically. Included are the spinal cord and nerve roots.

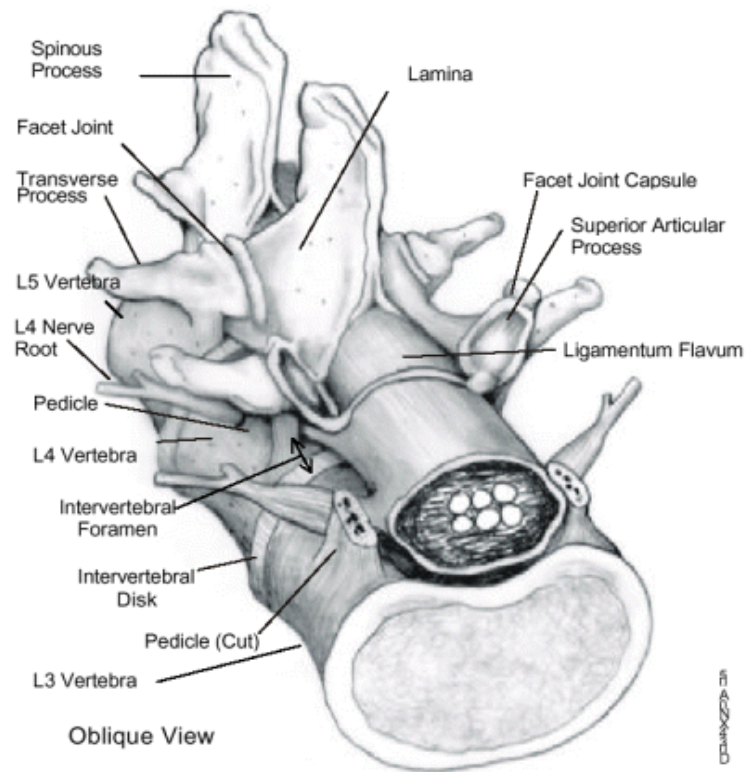


Figure 3. Oblique view of several vertebrae

In between each of the vertebral bodies is a fibrocartilaginous intervertebral disc. These discs are composed of an outer fibrous ring called the annulus fibrosus and an internal semifluid mass called the nucleus pulposus(Moore, 1992). The outer annulus fibrosus adds strength and support while the nucleus pulposus helps in absorbing shock from compressive forces. Figure 4 is a representation of an intervertebral disc as seen from the superior aspect.

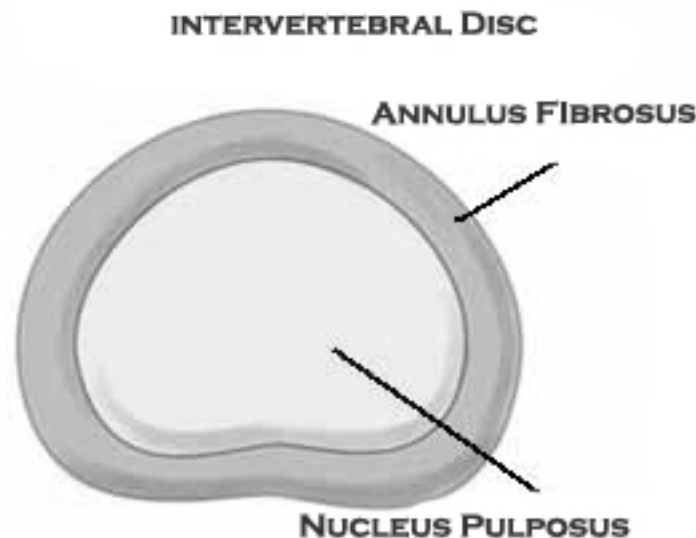


Figure 4. Intervertebral disc image

Modified from <http://www.spineuniverse.com/displayarticle.php/article1485.html>

Low back pain can be related to any one or more of these structures at a given time. There is also a subset of low back pain which is classified as nonspecific low back pain. This is explained by one study with the term “nonspecific” indicating no precise structure is identified as causing the pain. The common diagnoses covered by nonspecific low back pain include lumbago, myofascial syndromes, muscle spasms, mechanical LBP, back sprain and back strain(Nordin, Balague, & Cedraschi, 2006). The more common causes include musculoligamentous injuries, vertebral fractures, degenerative changes, spinal stenosis, anatomic anomalies, herniated intervertebral discs with nerve root compression, systemic diseases which

may include cancer and infection, and also certain visceral diseases unrelated to the spine(McCunney, 2003). For a better understanding of low back pain I will discuss the underlying pathology to the common causes listed above.

One of the most commonly encountered injury types to the lower back seen in an occupational setting would be the musculoligamentous injuries. As the name implies, these are injuries to the supporting musculature of the lower back and/or the ligamentous structures related to the lumbosacral spine. The injuries can be related to an acute traumatic event in which a patient will be able to specify a particular precipitating event leading to the current pain and injury.

The musculoligamentous injuries can also be related to cumulative microtrauma which occurs over a period of months to years. Eventually a threshold is reached where the normal functioning of the structures involved breaks down and the patient begins to experience pain. In this case there is often not a particular event which can be referred to as the precipitating event.

The next cause of low back pain is related to a fracture of one or more of the vertebral bodies in the lumbar spine. This can occur with trauma most frequently and is often related to compressive or loading forces on the spine. These would be considered compression type fractures. Avulsion type fractures can occur through large amounts of stress place on the ligamentous and muscular structures attaching to the bony spine. In this instance the tendinous or ligamentous attachment to the bony structure is strong enough to hold while the bone itself gives way and leads to a fracture.

Another cause of low back pain is one of degenerative changes or osteoarthritis. This cause of low back pain is related to cumulative trauma over years and is more commonly seen in older populations. Osteoarthritis of the spine occurs primarily in the cervical and lumbar spine

with the formation of osteophytes which can encroach on the neural foramina. There is often degenerative spondylolisthesis which is movement of a vertebral body anteriorly when compared to the vertebral body at the level below it(Weissleder, Wittenberg, & Harisinghani, 2003). Spondylolisthesis is another one of the causes of low back pain which was listed previously and does have other causes which are generally due to anatomic variations and not to injury.

The next cause of low back pain we will discuss is related to spinal stenosis. Spinal stenosis can be considered “narrowing of the spinal canal that occurs when excessive growth of bone and/or tissue reduces the size of the openings in the spinal bones”(WebMD). When the size of the spinal canal decreases there is increased pressure place on the spinal cord or nerve roots present at that level.

A herniated intervertebral disc with nerve root compression is another common cause of low back pain. When there is disc herniation, the nucleus pulposus protrudes through a defect in the annulus fibrosus. This protrusion can compress the spinal canal or impinge on nerve roots as they exit through an intervertebral foramen. This pressure causes irritation of the nerve causing it to become the source of what is called discogenic pain.

The other causes of back pain related to systemic and visceral disease need to be excluded before beginning treatment for work related low back pain. Pain caused by conditions such as cancer and infection are important not to miss and are some of the “red flags” which require a specialist outside of the field of occupational medicine.

2.2 IMPORTANCE OF THE PROBLEM OF LOW BACK PAIN AND LOW BACK PAIN RECURRENCE

The primary goal of this research is to establish a definition of low back pain (LBP) and its recurrence by consensus from a review of current research and medical literature. In the next step this definition will then be used in a study to determine the rate of LBP and LBP recurrence as well as associated costs to employers and insurers. The final step will be to evaluate the cost and effectiveness of different treatments and modalities on individuals with LBP.

This is important because frequent recurrences of LBP have an immediate effect on raising direct and indirect health care costs(Wasiak, Pransky, & Webster, 2003). One of the ways costs increase is by patients transitioning to chronic low back pain. This is detrimental to the overall outcome for patients, their employers, and their health plans. Recent work in the field has begun to focus on earlier intervention with functional restoration programs to avoid the transition from acute to chronic conditions. However, it is still unknown which factors predict better outcomes among patients enrolled in intensive rehabilitation programs(Gross & Battie, 2005). Our proposed work may also shed light on ways to help prevent the very high recurrence rates seen in studies examining low back pain.

One set of authors feels that the number of patients who are now unable to deal with back pain has reached epidemic proportions. They also feel current strategies aimed at “recourse and redress accounts for an astounding transfer of wealth, much of which is brokered by an enormous public/private enterprise charged with indemnification”(Hadler & Carey, 1998). This makes us aware of the fact that secondary monetary gains may be inextricably linked to the current situation of recurrent low back pain in Western countries. It is difficult to treat patients with low back pain if they have a financial incentive to continue to report pain and injury.

It is not hard to search the medical literature and come up with a large amount of articles which focus on back pain. 70-85% of all people will have back pain at some point in their life and the annual prevalence of back pain can range from 15-45% depending on the study(Andersson, 1999). In the United States for the year 1993 back pain represented one fourth of the lost work injuries and illnesses reported and overall LBP is the second most frequent cause of sickness absence in industrial populations(Hiebert, Skovron, Nordin, & Crane, 2003). In the United States alone LBP is the leading cause of visits to orthopedic surgeons, neurosurgeons, occupational medicine physicians, and osteopathic physicians(Ijzelenberg & Burdorf, 2005).

There are several facets to low back pain and many of them are not related to physical pathology. Most researchers agree that there is significant importance which psychological and social factors have in impacting the recurrence and chronicity of low back pain(Biering-Sorensen & Bendix, 2000; Elders & Burdorf, 2004). Studies have identified an association between psychological factors which include anxiety, depression, somatisation symptoms, stressful responsibility, job dissatisfaction, mental stress at work, negative body image, weakness in ego functioning, and poor drive satisfaction and the occurrence of low back pain(Andersson, 1999). Taking the biopsychosocial model of back pain into account one study suggests the underlying psychosocial factors need to be identified, those factors need to be treated with nontraditional interventions (behavioral treatment, ergonomic intervention) and the patient needs to be empowered to help manage their condition(Nordin, Balague, & Cedraschi, 2006).

Related to the psychological aspect is the finding that in some patients with chronic low back pain and no identifiable cause there may be what has been described as augmented central pain processing. One study found that patients with idiopathic chronic low back pain showed increased activation of neurons in pain-related cortical areas as compared to control

subjects(Giesecke et al., 2004). Essentially, these patients are more sensitive to painful stimuli which has a direct adverse effect on their outcome. This is especially true if the only treatment options available to them are traditional treatment modalities aimed at identifiable organic causes.

2.3 CURRENT CONTROVERSIES IN THE DEFINITION OF RECURRENT LOW BACK PAIN

One of the most pressing problems facing researchers and clinicians in evaluating low back pain recurrence is the lack of a consensus definition in the medical and research literature. The ability to recognize “true” recurrences is essential, as it would help to correctly identify the exact extent of pain and suffering resulting from LPB. It would also help in comparing alternative treatments and secondary prevention efforts based on such outcomes as recurrence(Wasiak, Pransky, Verma, & Webster, 2003). Because of the apparent lack of homogeneity in the various LBP definitions it is difficult for researchers and clinicians to compare the results of different studies and to reach definitive conclusions about low back pain recurrence(Hestbaek, Leboeuf-Yde, & Manniche, 2003).

One of the reasons the definitions of LPB and LBP recurrence differ is that by choosing a specific definition, researchers often attempt to maximize the usefulness of available data in order to validate their stated hypotheses(Wasiak, Pransky, & Webster, 2003). This creates confusion because there are literally hundreds of articles in the medical literature dealing with all aspects of LBP. These range from establishing mechanisms of injury to evaluation and treatment to the various incident rates of LBP in both the general and occupational populations as well as

the direct and indirect costs to society. Although these articles often examine large populations of patients and deal with the most advanced diagnostic and treatment modalities, their major limitations is a vague definition of LBP or LBP recurrence. A substantial number of studies even reported on LBP episodes without defining them(de Vet et al., 2002). Even taking this information into account, the findings of many studies on LBP and LBP recurrence are disturbing.

Without a consistent definition, results of studies vary greatly and their results cannot be reproduced when applied to populations which differ from the study population. This is evident as when analyzed in a study stating that large differences between the recurrence rates calculated in studies of LBP can be attributed to several factors, one of which is definitional differences in LBP recurrence(Wasiak, Pransky, & Webster, 2003). Having vague definitions of LBP and LBP recurrence makes it difficult for researchers and healthcare providers to truly evaluate what is in the best interest of the patients they serve. Different etiologies and causes of recurrent LBP add to the complexity of a definition of recurrent back pain and distinct episodes(de Vet et al., 2002). When researchers and clinicians are not able to accurately compare the results of different studies to assess the effectiveness of treatment and prevention measures confusing and contradictory assumptions are made. Also, results simply cannot be extrapolated to other populations which differ from a particular study population as previously stated.

Many of the studies classify low back pain with relation to the duration of the complaints (acute, subacute, and chronic) although, as we have discussed, these terms are often defined in many different ways. Additionally, LBP often runs a recurrent course that is neither acute nor chronic(van den Hoogen, Koes, van Eijk, Bouter, & Deville, 1998).

2.4 VARIOUS CURRENTLY USED DEFINITIONS OF RECURRENT LOW BACK PAIN

Of course with the large number of studies dealing with back pain in its various forms and the current lack of a universal definition of low back pain there are many definitions which have been used so far. In the study by Hiebert et al.,(Hiebert, Skovron, Nordin, & Crane, 2003) low back pain was considered to be “any period during which an employee lost time away from work or had normal work activities curtailed or modified because of reported back pain”. This study went on to define an episode as having ended when all work restrictions were lifted and the employee was returned to his or her usual job. More importantly for us recurrence was defined as “occurrence of a subsequent episode of back pain resulting in lost work time during a 1-year period after return to any work, including both restricted and unrestricted work”. Even though not specifically restricting his definition to low back pain Von Korff(Von Korff, 1994) describes chronic back pain being present on at least half of the days in a 12 month period either in single or multiple episodes. Recurrent back pain is defined as being present on less than half of the days in a 12 month period, again occurring in multiple episodes over the year.

One study based on analysis of administrative claims data identified four definitions of LBP recurrence found in the literature. Three are based on a specific event: pain, health care utilization, or time away from work (work disability). The fourth is contingent on the existence of repeated workers’ compensation claims(Wasiak, Pransky, Verma, & Webster, 2003). Table 1 summarizes these four definitions of low back pain recurrence.

Table 1. Low Back Pain recurrence definitions based on administrative claims data

Analysis of Administrative Claims Data		Definition
Definition based on specific event	Pain	Recurrent pain in the same area of the lower back
	Health Care Utilization	Recurrent treatment or episodes of care
	Work Disability	Recurrent sickness absence or episodes of compensated disability
Definition based on repeated Workers' Compensation claims	Workers' Compensation Claims	Claimed injury or episode of pain in the same general anatomic area that is considered a continuation of a previous rather than a new compensable incident

Using claims data one study defined recurrence as restarting total temporary disability (Canada), reopening a claim, or filing a new back-related claim within the year following a functional capacity evaluation (Gross & Battie, 2004). Another study applied a definition of an episode of LBP as a period of LBP preceded and followed by 1 month without LBP (de Vet et al., 2002). This does not speak directly to a recurrence but at least it helps in setting parameters for a single episode of low back pain. Yet another study defined a four week pain free period to define the end of an initial episode of LBP. Using the above definition for an initial episode of LBP a recurrence was defined as starting during the first week a patient reported having had low back pain again after a pain free period of four weeks or more (van den Hoogen, Koes, van Eijk, Bouter, & Deville, 1998). A fairly simple definition of LBP recurrence is provided with the term

reinjury which is defined as a recurrence of back pain resulting from or by an event on or off the job(Pransky et al., 2002).

More definitions for LBP and recurrent LBP in the literature include defining LBP as a person who experienced an episode of pain, stiffness, or discomfort of the lower back(Elders & Burdorf, 2004). It is interesting to note that this study by Elders and Burdorf uses the term lower back without explicit information on what is considered the lower back. This study was also one of the ones which defined LBP recurrence and classified it as an episode of low back pain in a given year subsequent to a previous year with similar complaints. Another study recruited patients with back pain of less than 12 weeks duration and had patients rate their pain on a visual analog scale of 0 to 100-mm. Those completing the study had recurrence defined as a pain score which returned to a level above 10(McGuirk, King, Govind, Lowry, & Bogduk, 2001). Additionally, a study examining adolescents classified recurrent non-specific low back pain as multiple acute episodes experienced as multiple spells(Jones, Stratton, Reilly, & Unnithan, 2005).

2.5 DIRECT AND INDIRECT COSTS ASSOCIATED WITH LOW BACK PAIN AND RECURRENT LOW BACK PAIN

One study notes that even though it is difficult to obtain accurate data the duration of work loss is important to the individual, their medical management, and the overall impact on society(Watson, Main, Waddell, Gales, & Purcell-Jones, 1998). It is estimated that in the United States almost 5% of all workers are affected with work-related low back pain (WLBP) each year. This results in more than 100 million lost workdays and direct costs of almost \$9 billion.

However, few data are available describing the effects of WLBP on other aspects of work functioning including job performance, satisfaction, motivation, and capacity; reinjury; job tenure; or concerns about future work(Pransky et al., 2002). Other studies also paint a grim picture of the economic impact low back pain has on employers and the healthcare system. Medical costs, loss of work, and disability costs add up to at least \$50 billion per year in the United States with approximately 2% of the U.S. workforce compensated for back injuries each year(G. S. Hicks et al., 2002).

The problem is not restricted to the United States alone. LBP and LBP recurrence are a problem throughout Western countries. A study done in the UK found the total cost for the benefits paid for back trouble during 1994 was £1,287,204, and the total cost of all sickness and invalidity payments for all claims of >1 day in the study area for 1994-1995 was £12.2 million(Watson, Main, Waddell, Gales, & Purcell-Jones, 1998).

2.6 RECURRENCE RATES OF LOW BACK PAIN

As with other information contained in the literature examined the rates of recurrent LBP have a fairly wide variability. As we see this is due to many factors including the data available for study, the research design of the study, the different populations under study, and the definitions used to describe LBP and recurrent LBP. One study which looked at exercise for treating a first episode of low back pain stated that 2-3% of patients eventually develop chronic symptoms related to their LBP and noted that the factors which lead to recurrence are little understood(Hides, Jull, & Richardson, 2001). Hiebert et al(Hiebert, Skovron, Nordin, & Crane, 2003) in their study on the outcome of nonspecific low back pain found that approximately 5%

of patients transitioned to a chronic condition of LBP of more than 6 months duration. While this does not explicitly speak to recurrence, chronic low back pain which appears episodically over time would fit some definitions already put forth for recurrent low back pain.

One study which specifically looked at differences in LBP recurrence rates found a fairly wide variability in the numbers based on the definition used. Using the definition of an episode of pain, derived from self-reported surveys, the recurrence rate was found to be as high as 35% for 6 month follow-up and 82% at one year. A definition based solely on workers' compensation claims showed lower recurrence rates of 5% at 15 months and 14% at 6 years(Wasiak, Pransky, & Webster, 2003). The caution here is that the true numbers may lie somewhere in between. This is because a recurrence defined by using workers' compensation claims does not compare to a definition of recurrence using health care utilization or repeated disability. The reason the numbers using workers' compensation claims and those using health care utilization and repeated disability do not match is because they are derived from two different sets of data. In general, workers represent a younger, healthier segment of the population.

The support for the true numbers lying in between comes from Gross and Battié(Gross & Battie, 2005) who found a 1-year recurrence rate ranging between 18% and 22%. Within this range are also results from McGuirk et al(McGuirk, King, Govind, Lowry, & Bogduk, 2001) showing 16% at one year in an evidence based study group and 27% in the control group of usual care.

The study by Elders et al(Elders & Burdorf, 2004) found recurrence for chronic low back pain to vary between 33% and 65%. The cumulative recurrence rate for LBP during the 3-year follow-up period of their study was 78%.

2.7 DIFFICULTIES IN DOCUMENTING RECURRENT LOW BACK PAIN

Now that we have outlined why the variations in the definition of LBP and LBP recurrence is a problem we can begin to explore the results of using various definitions in the medical literature. Because if the time of onset of LBP is not clearly defined, it is very difficult to distinguish between incidence and recurrence(Elders & Burdorf, 2004). This will help us understand some of the specific problems which may arise and to in turn prepare ourselves to address the problems and to begin to formulate a solution.

Specific examples of differing results from different definitions of LBP and LBP recurrences are not difficult to find. A surprising finding of one of the studies was that almost three of every four patients who completed the follow-up period of the study endured a relapse(van den Hoogen, Koes, van Eijk, Bouter, & Deville, 1998) which is higher than was assumed by the authors. Another study found that reinjury to the low back during a follow-up evaluation occurred in 42% of the study group(Pransky et al., 2002) which is a much lower number. The authors of this study did not explicitly define what constituted a reinjury but common usage would suggest an injury occurring to the same area after the initial injury had resolved.

Risk factors for LBP recurrence in various studies can be sensitive to the applied definition of LBP recurrence(Wasiak, Verma, Pransky, & Webster, 2004). By not having a standard definition of LBP recurrence the risk factors reported for LBP recurrence will vary just as the researchers' definition of LBP recurrence varies. This makes it difficult for clinicians to compare the results of what initially may appear to be similar studies. The real problem is that it makes it difficult for clinicians to then advise patients on what may affect them in having an episode of low back pain recurrence.

One of the reasons for the various definitions of LBP and LBP recurrence is that the data used in the various studies are either incomplete or derived from sources not specifically tailored to evaluating LBP. Therefore, the definitions are often tailored to derive the greatest benefit from the available data. This is especially true for retrospective studies.

One way to clarify the differences would be to define variations such as transient back pain, recurrent back pain, chronic back pain, acute back pain, first onset, and flare-up(de Vet et al., 2002). In the same article de Vet et al., provided two other definitions which may need to be standardized when reviewing data to analyze LBP. Care for low back pain is defined as a consultation or a series of consultations for low back pain, preceded and followed by at least three months without consultation for low back pain. A work absence due to low back pain is defined as a period of work absence due to low back pain, preceded and followed by a period of at least one day at work.

2.8 CURRENT TREATMENT OF LOW BACK PAIN AND RECURRENT LOW BACK PAIN

Low back pain in many cases should be viewed as a recurrent illness and therefore the treatment of LBP should be changed accordingly(van den Hoogen, Koes, van Eijk, Bouter, & Deville, 1998). Another factor which should be kept in mind is that recurrent low back pain is not a static condition and both pain and the episodic nature of LBP can have an effect on disability(McGorry, Webster, Snook, & Hsiang, 2000). Being able to analyze LBP recurrence is likely to contribute to a better understanding of risk factors involved and lead to better prevention(Wasiak, Pransky, & Webster, 2003). To reduce chronicity, disability, and cost,

preventive measures should be explored because so far attempts to prevent the occurrence of back pain (primary prevention) have been unsuccessful and prevention of the negative consequences of a back-pain episode may be more fruitful(Andersson, 1999). A focus of prevention should be on preventing the socioeconomic consequences of disability resulting from low back pain rather than on its onset(Ijzelenberg & Burdorf, 2005).

One of the ways to prevent some of the negative consequences of LBP is through the use of exercise as a treatment option. A study examining exercise and pain recurrence for low back injuries found that those who maintained regular exercise habits after the treatment for their back pain had fewer recurrences of persistent pain and less work absenteeism. There was also a significantly better treatment outcome concerning pain intensity among those who later participated in physical training than among those who did not(Taimela, Diederich, Hubsch, & Heinricy, 2000). This finding is supported by another study which looked at spinal stabilization exercises. It found that for patients with acute first episode LBP, specific spinal stabilization exercise substantially reduces the risk of recurrences in the long-term compared to subjects who received only medical management(Hides, Jull, & Richardson, 2001). One common form of exercise therapy for back pain is McKenzie therapy. The McKenzie method uses patient exercise for neck and back pain preferably taught by a trained physical therapist. It has been shown that McKenzie therapy can result in a decrease in short term (<3 months) pain and disability for low back pain compared to other standard treatments(Busanich & Verscheure, 2006).

However, the above information must be evaluated against the information derived from another study by Koumantakis et al which compared stabilization exercises to a general exercise program. This particular study found that stabilization exercises did not provide any additional benefits over general exercise to patients with subacute or chronic low back pain(Koumantakis,

Watson, & Oldham, 2005). Therefore the results seen for stabilization exercise are likely best achieved if used in patients who have some suggestion through clinical evaluation of spinal instability. At this time it is still unknown which factors predict better outcomes among patients enrolled in intensive rehabilitation programs(Gross & Battie, 2005) and this is one of the questions our research would hope to answer.

A study by Jones et al(Jones, Stratton, Reilly, & Unnithan, 2005) may shed some light on where to start looking for factors predicting a better outcomes by identifying risk factors for recurrent low back pain. The study involved adolescents but found four biological risk factors for recurrent low back pain. These are: hip range of motion, abdominal muscle endurance, lumbar flexibility, and lateral flexion of the spine. Lumbar flexibility and lateral flexion of the spine are already commonly used in practice to evaluate patients with low back pain especially in injured workers. Following along this line of reasoning better outcomes may also be achieved by using a classification-based therapy for patients. Classification-based therapy seeks to group patients to a specific treatment group based on their presenting examination findings. This is supported by research which shows that classification-based therapy can result in better outcomes for patients when measured for disability, return to work, and patient satisfaction compared to standard treatments based on clinical practice guidelines(Fritz, Delitto, & Erhard, 2003). Similar results were obtained when subgroups of patients were identified based on signs and symptoms from the clinical examination. This resulted in better clinical outcomes for patients when subgroups were used to guide treatment decisions(Brennan et al., 2006).

Another treatment available to physicians involved in the care of patients with recurrent LBP is the use of time off from work or work restrictions. It is now almost universally accepted that the sooner a patient can return to work, either with or without restrictions, the better chance

they have of not transitioning to long term disability. While bed rest and time off from work are no longer considered helpful and have even been shown to be detrimental, the use of work restrictions is acceptable. The rationale behind this concept is to allow the patient to continue to work yet remove them from the harmful or triggering stresses of their job. This is advice found in many guidelines which feel the provision of advice to the patient should be a first line of care. The advice includes reassuring the patient of a favorable prognosis for their condition and encouraging them to stay active and discouraging bed rest(Hancock et al., 2005).

This seems to be a very logical conclusion to make about work restrictions; however, there are very few studies which have actually evaluated the usefulness of work restrictions in those suffering with low back pain. At least one study which examined work restrictions found that employees placed on restricted work took 47.5 days to return to unrestricted work. Those employees without prescribed work restrictions took only 15 days to return to unrestricted work(Hiebert, Skovron, Nordin, & Crane, 2003). The exact explanation for these results is not known, however, in this study only worker age, gender, job category, and race were adjusted in the analysis. It did not mention severity of the pain as reported by the patient and this may be a variable which needs to be included for analysis in future research. The classification of severity of any type of pain is a very subjective measure and this is especially true for low back pain. There are a wide variety of pain scales available for use by researchers and the use of a particular scale may have an effect on the outcome of a study.

Another example of how information is lacking or incomplete comes from a study which demonstrated that better performance on functional capacity evaluations as defined by a lower number of failed FCE tasks was associated with higher risk of low back pain recurrence. This

means that evaluating patients with FCE to identify those who could safely return to work is not supported by the findings of the study(Gross & Battie, 2004).

The guideline developed by the Agency for Health Care Policy and Research notes that comfort is the patient's first concern. To this end it recommends nonprescription analgesic should be tried first with progression to prescription medications as needed. Acetaminophen and NSAIDs such as aspirin and ibuprofen are the preferred first line option(Research, 1994). If these do not provide adequate relief muscle relaxants may be of benefit to some patients. The guideline notes that opioids do not appear to be more effective than other analgesics for the management of low back pain. One study found the use of opioids was associated with high volume usage of other low back pain services such as physical therapy services, MRI or CT, ED visits, spinal injections, or admission to the hospital(Vogt et al., 2005). Further studies may be needed to address this association especially in light of the fact that the use of opioids in current literature does not provide a superior benefit to the patient. Table 2 on the next page shows the nonprescription and prescription treatment options for patient symptom control.

Table 2. Recommendations for patient symptom control

Recommended Symptom Control Methods	
Nonprescription analgesics for:	
Nonspecific low back symptoms and/or sciatica	Nonspecific low back symptoms
Acetaminophen (safest) NSAIDs (Asprin[1],Ibuprofen[1])	
Other NSAIDs[1]	Manipulation (in place of medication or a shorter trial if combined with NSAIDs)
Options for:	
Nonspecific low back symptoms and/or sciatica	Nonspecific low back symptoms
Muscle relaxants [2,3,4]	Physical agents and modalities [2] (heat or cold modalities for home programs only)
Opioids [2,3,4]	Shoe insoles [2]
1. Aspirin and other NSAIDs are not recommended for use in combination with one another due to the risk of GI complications. 2. Equivocal efficacy. 3. Significant potential for producing drowsiness and debilitation; potential for dependency. 4. Short course (few days only) for severe symptoms.	

The guideline(Research, 1994) also lists other treatments which are often encountered in the initial treatment of a patient with low back pain. These include manipulation, traction, physical modalities (massage, diathermy, ultrasound, cutaneous laser treatment, biofeedback, and transcutaneous electrical nerve stimulation (TENS)), invasive techniques (needle acupuncture and injection procedures).

Figure 5 on the next page from the guidelines(Research, 1994) lists an initial low back pain treatment and follow-up algorithm.

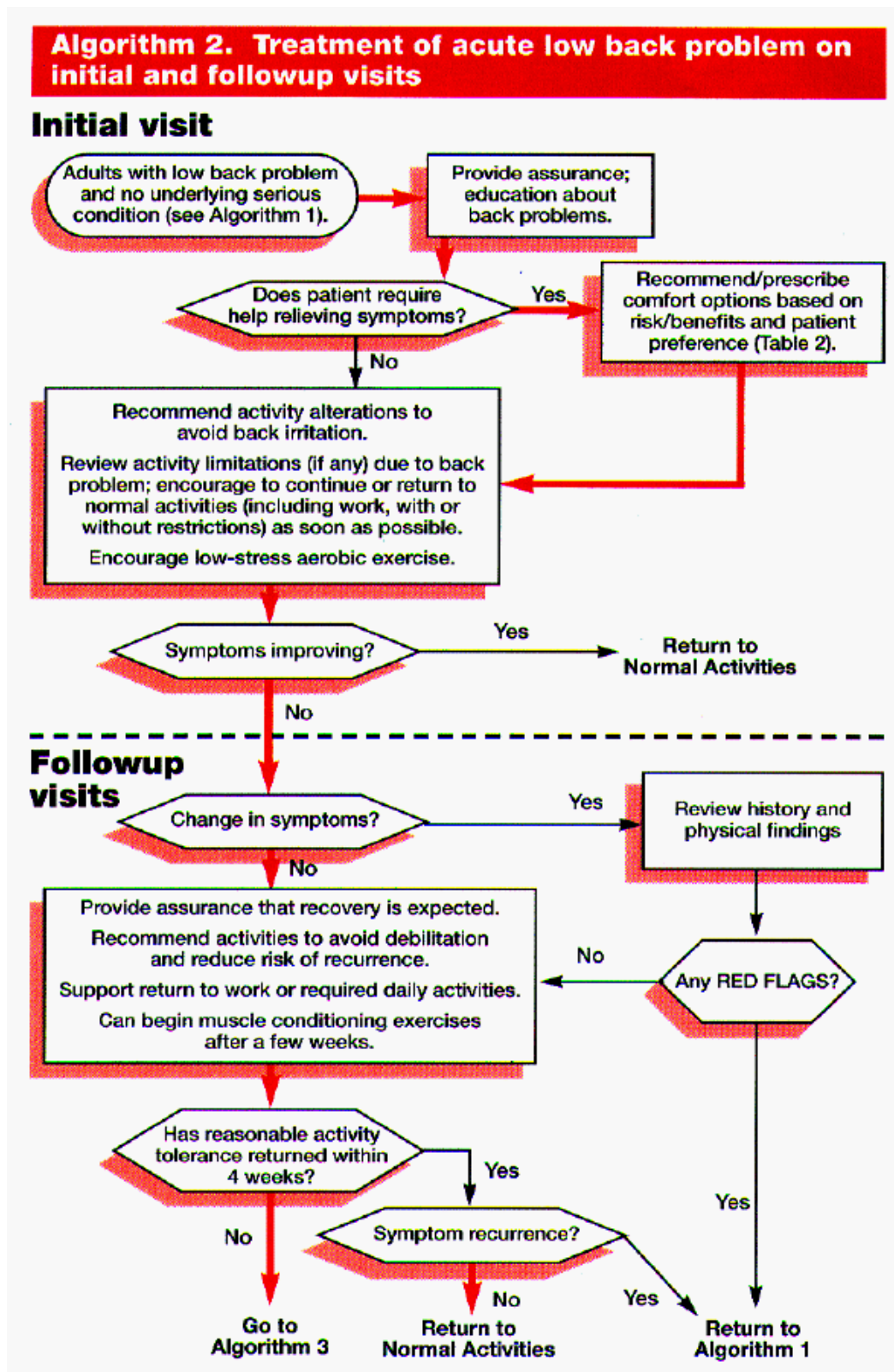


Figure 5. Initial low back pain treatment and follow-up algorithm

This figure references algorithms 1 and 3 which can be found in the appendix. A complete set of the algorithms from the Agency for Health Care Policy and Research (AHCPR) for Acute Low Back Problems in Adults: Assessment and Treatment (Research, 1994) can also be found in the appendix.

Surgery is another treatment option for recurrent low back pain but as one study found there was not substantial evidence that primary spinal fusion was any more beneficial than intensive rehabilitation (Nordin, Balague, & Cedraschi, 2006). Our study looks to keep recurrence rates down through nonsurgical treatment and, therefore, the different types of surgical intervention will not be specifically addressed.

3.0 RESEARCH DESIGN AND METHODS

This observational study will take advantage of the large data bases of both the UPMC Health Plan as well as the self-insured workers' compensation fund of the UPMC. The study will be conducted in three distinct phases: (1) we will first formulate a definition of recurrent low back pain taking into consideration the data fields within both the commercial UPMC Health Plan as well as the Workers' Compensation data bases; (2) we will then calculate the incidence of recurrent low back pain in the combined data bases and then estimate the cost of recurrent low back pain on a yearly basis and (3) we will implement a spinal stabilization program to a targeted group of individuals who are believed to be at risk for recurrent low back pain and then reassess recurrence and costs after one year.

3.1 PROCEDURES FOR DEVELOPING A DEFINITION OF RECURRENT LOW BACK PAIN AND CALCULATING THE INCIDENCE AND COSTS OF RECURRENT LOW BACK PAIN

Though recurrent low back pain may seem to be easily defined clinically, we must keep in mind that we are solely dependent on the data that is already included in the combined data bases of the UPMC Health Plan and the Workers' Compensation areas. We know that data common to both data bases used the ICD9 codes. All of the ICD9 codes will be identified and coded to identify patients who have an episode of care due to a low back problem. From the literature, we

have deduced that a reasonable definition of low back pain recurrence is more than 2 episodes of low back pain within a 12 month period. Thus, we will identify all patients from the combined data bases from the UPMC Health Plan and the Workers' Compensation data bases with ICD9 codes for low back pain who have more than 2 episodes within a 1-year period. We will calculate all costs due to these multiple episodes of low back pain and compare these costs to low back pain costs of all other patients with low back episodes.

The uniqueness of this study lies in the combined data bases of the commercial UPMC Health Plan and its Workers' Compensation counterpart. By combining these data bases, we will have a more complete view of recurrent low back pain because we will be able to capture patients who have a low back pain episode claimed on the commercial UPMC Health Plan product and who subsequently have another claim on the Workers' Compensation product. Thus, the combined data base will allow us to look at a complete data set analogous to a single payer.

After analyzing the data as described above we will assess how well a spinal stabilization program to a targeted group of individuals performs relative to those who are believed to be at risk for recurrent low back pain or who have had two or more episodes of low back pain in a 12 month period. We will then reassess recurrence and costs after one year of treatment in the spinal stabilization group and compare that data to recurrence and cost relative to those undergoing standard treatment. A spinal stabilization program has been chosen for our intervention group because research has supported its use (G. E. Hicks, Fritz, Delitto, & McGill, 2005; Hides, Jull, & Richardson, 2001; Koumantakis, Watson, & Oldham, 2005) and the physical therapy facilities and personnel are readily available within the UPMC Health Plan system.

3.2 HUMAN SUBJECTS

The first and second parts of this study are an observational study of practice as it occurs in an everyday environment. Thus, we will be seeking exempt status from the Institutional Review Board. We believe this study complies with expedited review because this research is conducted on data derived from patients' medical records and other research or clinical records. The investigators can review these records because they have a legitimate right to access them. However, we will not record any private identifiable information from these records. To further ensure patient confidentiality, we intend to use the UPMC Health Plan as an honest broker in order to carry out this research, as this research involves the collection or study of existing data from the health plan. The honest broker will ensure that the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

The third part of the study, implementing a spinal stabilization program, if carried out, will require an IRB review. In this stage of the study there will be an interventional aspect by assigning patients to standard treatment or the spinal stabilization treatment program. Since the stages of the study are separate we will be able to perform the first two parts with an exempt status from the IRB. After analyzing the data obtained it will then be decided if the third stage will be pursued and at that time the IRB will be consulted on the use of human subjects.

4.0 PROPOSALS FOR THE FUTURE STUDY OF RECURRENT LOW BACK PAIN

The initial study outlined in the previous chapter will allow us to get a first look at the data available in the commercial UPMC Health Plan and its Workers' Compensation counterpart for an observational study. This information and results which will be obtained will be invaluable to the advancement of our knowledge in effectively treating and preventing recurrent low back pain. Recurrent low back pain has been such a difficult area for clinicians and researchers to effectively address due to the many definitions of the problem and the variability of research results as has been outlined previously in this paper.

The variability of results is not only due to the myriad of low back pain recurrence definitions but also to the way data for this condition is gathered and stored. The future of the field lies in creating an accepted definition of low back pain recurrence. With such a definition established the next step will be to create ways of looking at currently available data in light of our new definition or gathering data in new and different ways for future analysis.

In the following sections I hope to outline my rationale for a new universally accepted definition of recurrent low back pain. Building on that definition I will give a brief outline of a step-wise process to be used by future researchers in addressing recurrent low back pain. The scope of the future research will depend on many factors not the least of which will be available funding. Participation by a variety of entities such as large private and nonprofit hospitals,

community hospitals, clinician groups, and federal, state, and local government is essential to provide the resources and coordinated effort which is needed.

4.1 REACHING A DEFINITION OF RECURRENT LOW BACK PAIN

After having gone through the stages of examining the problem recurrent LBP creates for industry and society in general we need to begin our research by first setting up a definition of recurrent low back pain. The first and perhaps easier part of this task is to define low back pain. Many of the articles researched and cited use the term low back pain but a specific delineation of what is considered to be the low back is lacking. For our purposes I propose to define low back pain while including terminology to indicate what we mean by the anatomic area of the low back. Therefore, **low back pain is new onset of pain in the lumbar spine and paraspinous muscles, sacrum, or sacroiliac joints for which a patient requires time off work, assignment to restricted duty, seeks medical treatment, or has activities of daily living adversely affected by the pain.** Identifying patients who fit this definition of low back pain while at the same time excluding those who do not fit the definition is a difficult task. Through the use of patient questionnaires and examinations by trained clinicians I am confident this is a reasonable definition to use for low back pain in future research.

The next and perhaps more difficult portion of our task is to define what we consider a recurrence. This definition will include the above definition of low back pain but will add the modifier of recurrence to establish what we consider to be a repeat episode of the pain. Taking this into account I propose to define **recurrent low back pain as low back pain that reoccurs**

in the same anatomical location and occurs after a pain free period of at least 1 week or after returning to work without restrictions for 4 weeks or being discharged from medical treatment as having the current episode resolved. I have proposed the longer 4 week period for a return to work without restrictions before calling it a recurrence to differentiate a recurrent episode of low back pain from what may be considered a continuation of the same low back pain episode. Specifically to not confuse a patient returned to full duty before they are ready and experience an exacerbation of the current episode rather than a true recurrence.

Using the above definitions it might be easy to just conclude that any back pain lasting longer than one short-term event should be called chronic low back pain. For clarity I would argue then that chronic low back pain is almost continual low back pain which varies over time in intensity. Patients with chronic low back pain may also have pain free periods but these periods would be on less than half of the days for a given year. Chronic low back pain may also appear in a course of multiple episodes but the temporal spacing of these episodes would be such that it does not fit into our definition of recurrence.

With these various definitions we can already begin to see what trouble may arise in applying them to research and interpreting data for study. Any patient with two episodes of back pain in the same location then would fit into the recurrent low back pain criteria even if those episodes were far removed over a long period of time. To clarify this situation, any recurrence of pain after a pain free period greater than 12 months would constitute a new episode of low back pain.

One study had recommendations for researchers to keep in mind for future studies(Hestbaek, Leboeuf-Yde, & Manniche, 2003) and I have applied those recommendations to Table 3. The table also includes the reason those recommendations are important.

Table 3. Recommendations for future studies

Recommendation	Reason for recommendation
Provide a clear definition of low back pain	Avoids ambiguity and allows for comparison between studies
Provide subsets of data for various LBP subgroups	allows for analysis along many dimensions of study
Where relevant, report clearly what constitutes a “recurrence”	Gives a definition which can be used to compare the results to previous and future studies
If possible report raw data	Allows for others to see how the conclusions were reached
Where relevant, discuss limitations of the chosen cohort and choice of outcomes measures	Helps in using the study to compare to future studies and to explain why differences in results may occur

4.2 PROCEDURES FOR BASELINE EXAMINATIONS

To begin the examination of any patient presenting with an occupational injury, whatever the complaint, a focused injury history must be obtained. This focused history should pertain to the mechanism of injury and work relatedness. Information should include the onset and quality of the pain. It should also focus on similar injuries in the past. Outside issues such as family and psychosocial stressors should be addressed and an assessment of the patient’s understanding of the injury should be elicited.

Next, a focused physical examination is needed. This physical examination should initially be used to rule out any “red flags” such as radiculopathy, possibility of fracture, infection, or malignancy. The Table 4 on the following page provides a list of potential “red flags”.

Table 4. Red flags for potentially serious conditions

Possible fracture	Possible tumor or infection	Possible cauda equina syndrome
From medical history		
Major trauma, such as vehicle accident or fall from height.	Age over 50 or under 20.	Saddle anesthesia.
Minor trauma or even strenuous lifting (in older or potentially osteoporotic patient).	History of cancer.	Recent onset of bladder dysfunction, such as urinary retention, increased frequency, or overflow incontinence.
	Constitutional symptoms, such as recent fever or chills or unexplained weight loss.	Severe or progressive neurologic deficit in the lower extremity.
	Risk factors for spinal infection: recent bacterial infection (e.g., urinary tract infection); IV drug abuse; or immune suppression (from steroids, transplant, or HIV).	
	Pain that worsens when supine; severe nighttime pain.	
From physical examination		
		Unexpected laxity of the anal sphincter.
		Perianal/perineal sensory loss.
		Major motor weakness: quadriceps (knee extension weakness); ankle plantar flexors, evertors, and dorsiflexors (foot drop).

Provided any “red flags” have been eliminated as a cause of the low back pain the clinician can then proceed with the examination. The neurovascular status of the lower extremities needs to be evaluated along with flexion, extension, and lateral bends and twists of the lumbar spine. Inspection for areas of muscle spasm and loss of the lumbar lordosis should also be used. Attention to the patient’s gait and balance are also essential.

4.3 TREATMENT AND FOLLOW-UP

After the initial evaluation patients will be classified into treatment groups based on their examination findings. The treatment groups will range from conservative therapy to an intensive spinal stabilization program. Research has shown that the patients who respond best to spinal stabilization can be identified through testing of four variables. These are: positive prone instability test, aberrant movements present, average straight leg raise greater than 90°, and age greater than 40 years old(G. E. Hicks, Fritz, Delitto, & McGill, 2005). A prone instability test is given by trained clinicians and notes pain when the patient is tested in two different positions. Aberrant movements consist of an instability catch, painful arc of motion, “thigh climbing”, or reversal of lumbopelvic rhythm(G. E. Hicks, Fritz, Delitto, & McGill, 2005).

A primary concern will be patient comfort and the use of NSAIDs initially is recommended with progression to other medications as needed. Activity as tolerated and work restrictions will be used based on the patient’s job description. Patients can also be advised on the use of ice and or heat on an as needed basis. To help with resolution of symptoms as soon as possible the initial treatment should also seek to address any psychosocial issues as well as any fear avoidance the patient may have related to their condition.

One of our focuses will also be to start early interventions with targeted back and trunk stabilization exercises and physical therapy using trained therapists. This has been shown to be effective and is a facet of future research which should not be overlooked. It is through this use of early intervention with stabilization exercises and physical therapy that the most benefits can be derived. All of this is done keeping in mind that cost effectiveness is an ever important issue.

Routine weekly follow-up will allow for evaluation of the patient’s progress and to address issue which may arise. The issues may be related to the injury itself, the job, or outside

factors which can all have a very large impact on the healing process. During the weekly follow-ups lack of progress can be identified and additional diagnostic testing or therapy can be recommended in a timely manner.

After the resolution of an episode it will be important to keep in touch with patients to evaluate for any episodes of recurrence. Every effort should be made to minimize loss to follow-up so that an accurate assessment of recurrence rates can be made.

In the end the analysis of the data and the patients' outcome will show the cost savings associated with this type of treatment program. Expected areas of cost savings would include less money spent on imaging studies such as plain radiographs and CT, less money spent on prescription medications, and less money spent on physical therapy. The reduced costs of imaging studies would come from their utilization not as a first line investigation but for those cases where treatment had failed and other pathology must be investigated. Savings on prescription medications would come from appropriate use of NSAIDs and narcotics as well as quicker resolution of pain requiring these medicines. Finally, the costs savings on physical therapy would come from identifying the patients who will benefit from treatment and directing them to that treatment early on in the course of their therapy.

The data gathered can also be analyzed in ways to help improve the process and identify those modalities which show the most effectiveness in preventing low back pain recurrence. As with any medical condition, the way the problem of low back pain recurrence is treated currently will change in the future with advancements in prevention, diagnosis, and treatment.

5.0 CONCLUSION

After reviewing the current literature on recurrent low back pain it is easy to see the complexity of the issue facing current researchers and clinicians. There are multiple definitions in use for recurrent low back pain leading to variable rates of recurrence reported in the literature. The variety of definitions in use is not the only problem. Currently most data used for research does not include all of the variables which would make for an ideal study looking at recurrent low back pain. The best is being done with what is available and researchers are aware of the limitations placed on them by using data from many disparate sources. The central aspect of this problem is that it makes it difficult to evaluate treatment regimens for patients and to conclude definitively which therapies will result in the best outcome for a particular patient in preventing low back pain recurrence.

This grant proposal takes the first step in solving this problem by combining two very large data bases from a commercial health plan and from workers' compensation. By evaluating this data set we can capture patients who may switch between the commercial and workers' compensation plans and avoid a certain amount of loss to follow-up which can hamper research only evaluating one or the other. This allows for a more thorough analysis of the data and more robust conclusions.

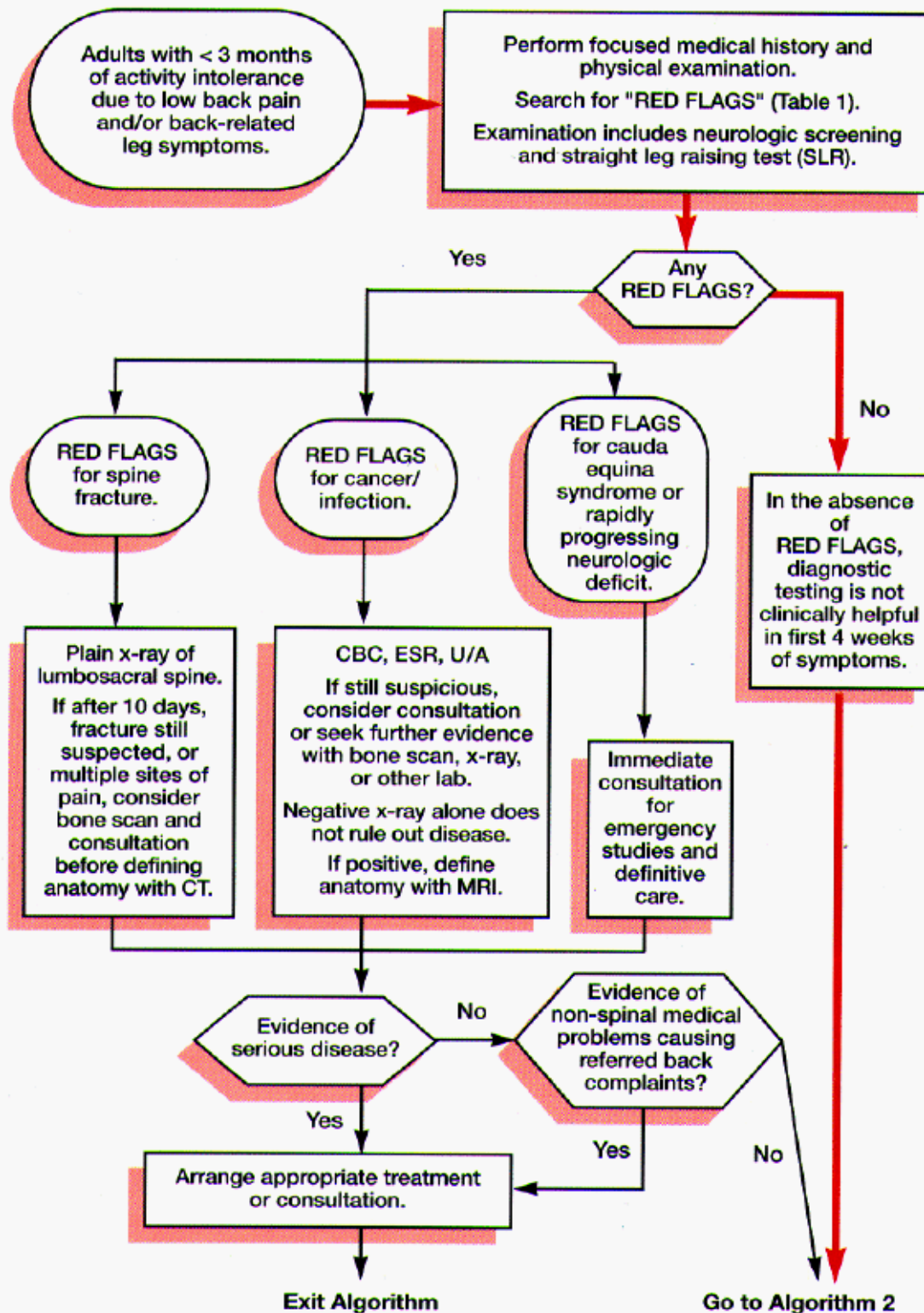
I have also taken this reasoning one step further by proposing a more complete definition of low back pain and low back pain recurrence for use in future studies. The definitions are based

on the large amount of literature available on the subject and seeks to consolidate the very best from each. I follow my proposed definitions with a brief outline of the selection, evaluation, and treatment of patients which can act as a framework for future researchers not only in study design but also in the creation and recording of data for low back pain research in the future.

APPENDIX

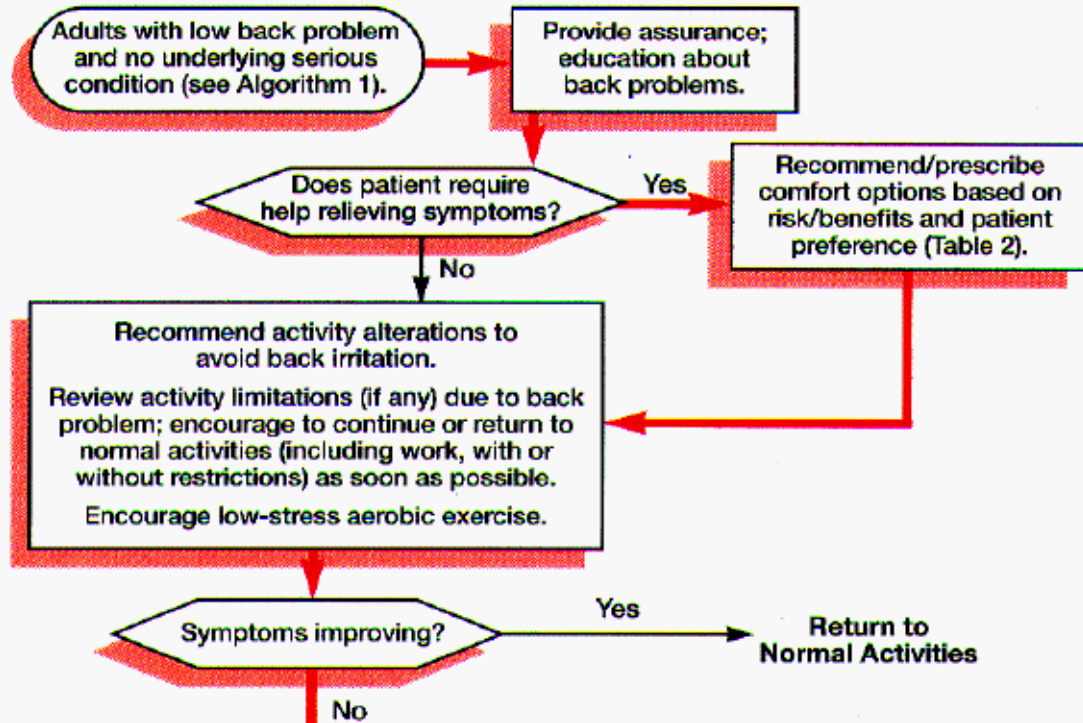
BACK PAIN ALGORITHMS

Algorithm 1. Initial evaluation of acute low back problem

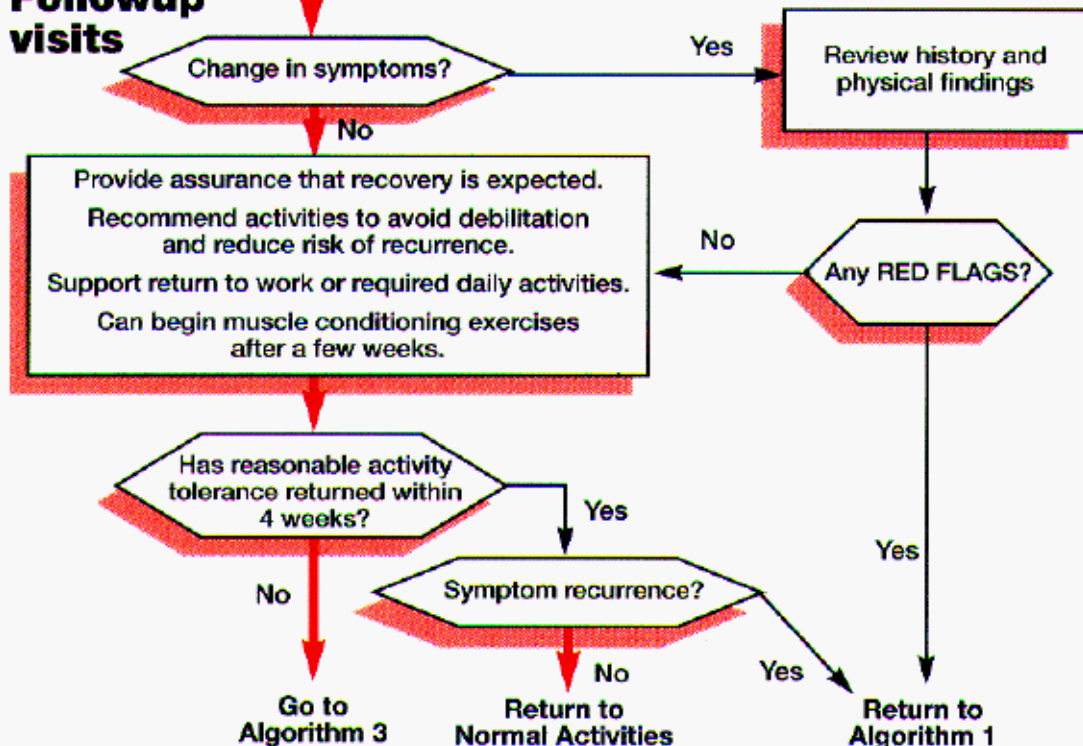


Algorithm 2. Treatment of acute low back problem on initial and followup visits

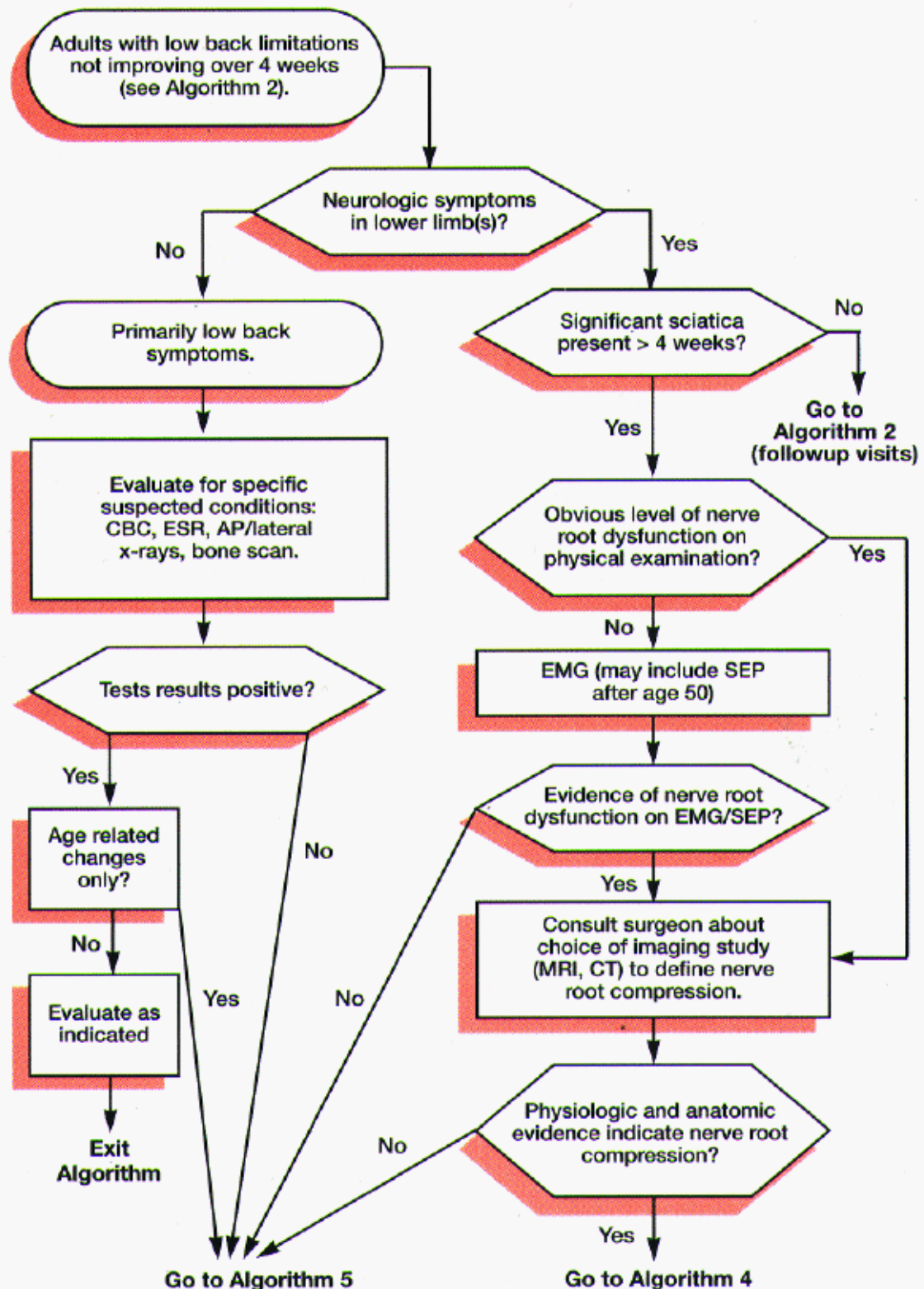
Initial visit



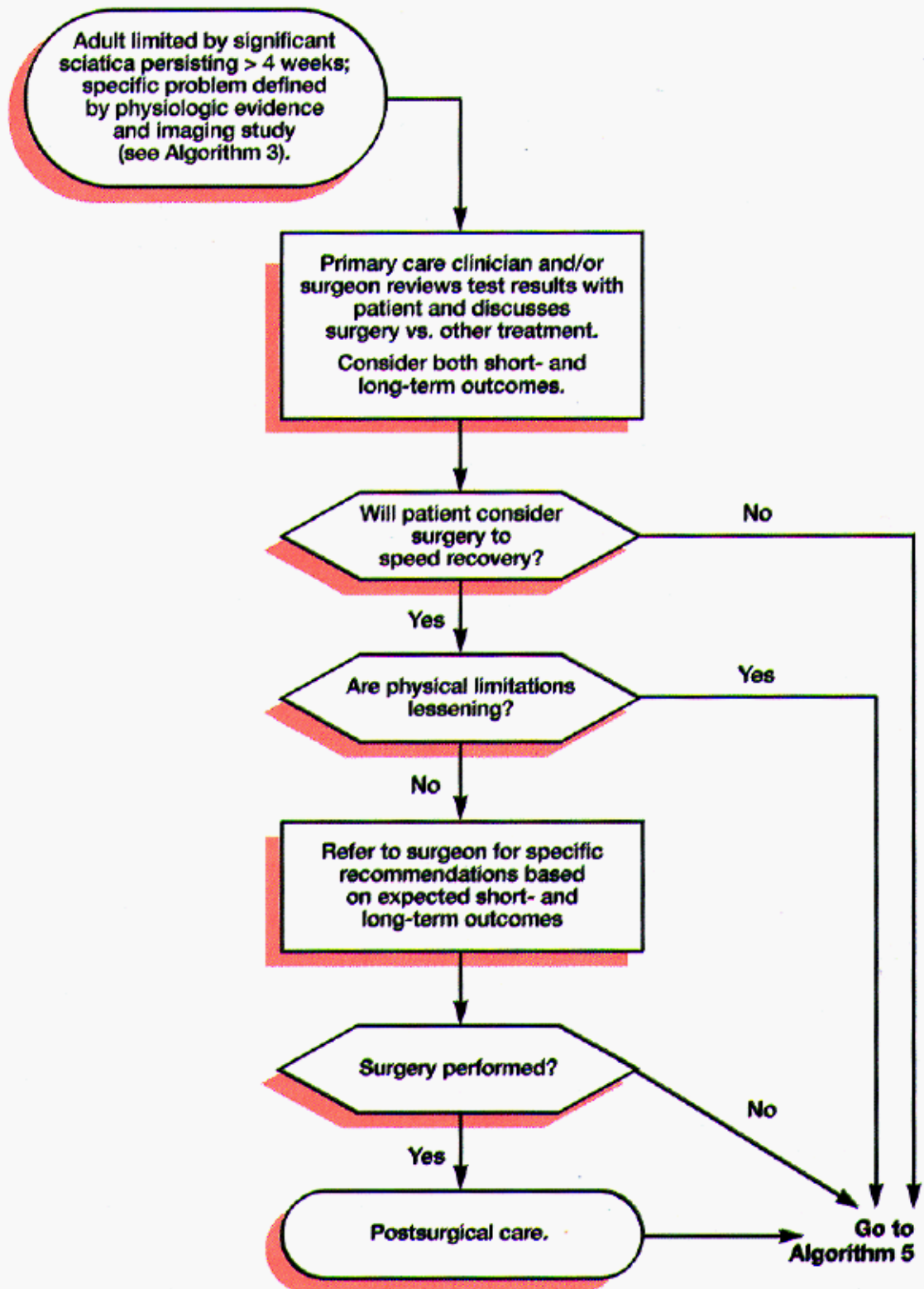
Followup visits



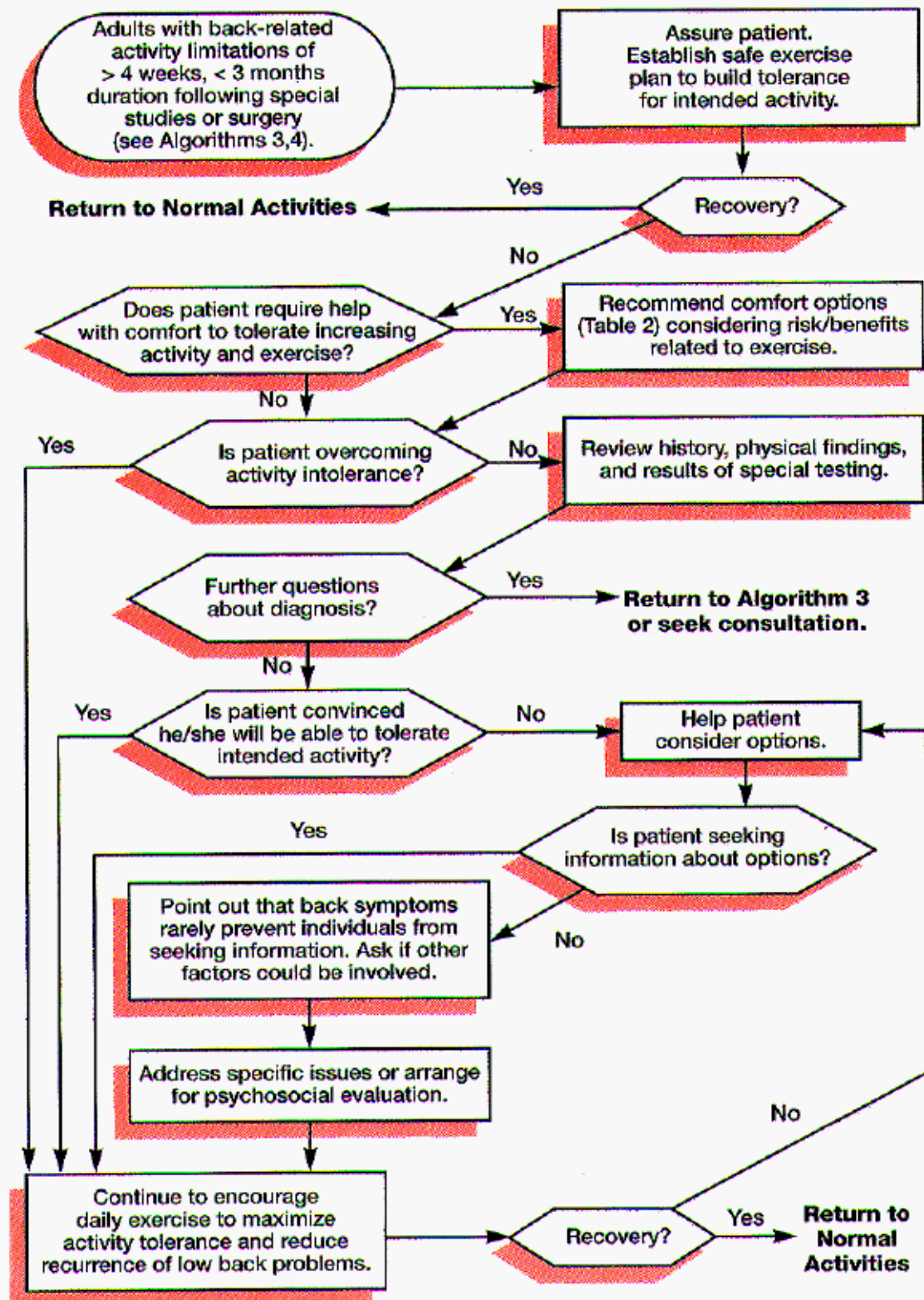
Algorithm 3. Evaluation of the slow-to-recover patient (symptoms > 4 weeks)



Algorithm 4. Surgical considerations for patients with persistent sciatica



Algorithm 5. Further management of acute low back problem



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